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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/419,611 10/18/99 IZUI

H 0010-1045-0

EXAMINER

HM12/0313

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TUNG, P.  
ART UNIT PAPER NUMBER1652  
DATE MAILED:6  
03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/419,611

Applicant(s)

Izui et al.

Examiner

Peter Tung

Group Art Unit

1652



Responsive to communication(s) filed on \_\_\_\_\_.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-4 is/are rejected.

Claim(s) 5 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

1. Claims 1-5 are pending.

### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): A computer readable form (computer disk) with the sequences of the Sequence Listing has not been submitted.

### ***Claim Objections***

4. Claim 4 is objected to because of the following informalities: “*agglomerans*” is misspelled. Appropriate correction is required.
5. Claim 5 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

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***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 3 is indefinite as it is unclear how “which” in line 3 of the claim connects the two phrases of the instant claim.

9. Claim 4 is indefinite as to the metes and bounds of the bacterium claimed by the use of “belongs to” in line 2. Replacing “belongs to” with “is” would overcome this rejection.

10. Claim 5 is indefinite because it depends upon an indefinite base claim and fail to correct the problem.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an enterobacteria containing DNA encoding *Brevibacterium lactofermentum* citrate synthase, does not reasonably provide enablement for an enterobacteria

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containing DNA encoding any coryneform bacterial citrate synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The breadth of the claims encompass an enterobacteria comprising DNA encoding coryneform citrate synthase. However, insufficient guidance is provided on how to obtain DNA encoding citrate synthase from other than *Brevibacterium lactofermentum*. Insufficient examples are provided of DNA encoding citrate synthase from other than *Brevibacterium lactofermentum*. The skill of those in the art is low in obtaining a DNA encoding coryneform citrate synthase when provided only with how to obtain DNA encoding *Brevibacterium lactofermentum* citrate synthase. Undue experimentation would be required to enable the full scope of the claims based upon the liming scope of the instant disclosure.

13. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. Adequate description for the species encompassed by the claim would have relevant identifying characteristics which include 1) structure, 2) physical and/or chemical characteristics, 3) functional characteristics when coupled with a known or disclosed correlation between function and structure, 4) a combination of these. The instant claims are drawn to an enterobacter containing a gene encoding a coryneform citrate synthase. However, the structure of a gene entails more than just the coding sequence of a protein but also includes the regulatory, promoter and terminator sequences that precede and follow the coding sequence. Adequate description of the structure of the gene would include all of these sequences. The instant application appears to only provide the coding sequences of DNA but not regulatory, promoter and terminator sequences. Therefore the complete structure of the gene is inadequately described.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata et al. (cited in IDS) in view of Moriya et al. Katsumata et al. teach (abstract0 microorganisms containing DNA encoding corynebacterium citrate synthase. Katsumata et al. teach that these microorganisms are used to produce glutamic acid. Katsumata et al. do not teach *Klebsiella planticola*. Moriya et al. teach (Column 2, lines 45-52) *K. planticola* for the production of glutamic acid involving citrate synthase. Moriya et al. do not teach DNA encoding corynebacterium citrate synthase. A *Klebsiella planticola* comprising DNA encoding corynebacterium citrate synthase would have been obvious to one of ordinary skill in the art at the time the invention was made for the benefit of a microorganism which can be used in glutamic acid production. One of ordinary skill in the art would have a reasonable expectation of success at doing this as transformation of bacteria is well known in the art. Therefore the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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